K110430

MAY 1 1 2011

5.0 Executive Summary

Dolphin Imaging software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

The software contains eight major components (modules) for achieving its basic functionalities. They are ImagingPlus™, Ceph Tracing, Treatment Simulation, Arnett/Gunson FAB, McLaughlin Dental VTO, Impanner™, Dolphin 3D, and Dolphin Letter System.

ImagingPlus™ is the foundation of the Dolphin product suites. It allows the user to capture, organize, edit, print, store and present patient image records. Acquisition of 2D image data can be performed from multiple types of devices, including digital radiography devices such as x-ray machines, generic imaging devices that support the TWIN interface standard, such as flatbed scanners and standard image file formats (Jpeg, Bitmap, etc.) stored on a computer, camera memory card or similar. Once acquired, images can be cropped, rotated, enhanced and otherwise manipulated before being stored in the corresponding patient record in the Dolphin Data Storage.

Ceph Tracing allows the user to digitize landmarks on a patient's radiograph, trace cephlometric structures, view cephalometric measurements, and superimpose images for analysis. If a suitable image (lateral x-ray, frontal x-ray, or arch view) has been acquired, the cephalometric digitizing module can be utilized to define a number of landmarks to establish the locations of specific anatomical features. The inter-relational positions of these landmarks are used to render tracing lines and calculate cephalometric measurements used in diagnosing patients and planning orthodontic and/or surgical procedures. If a patient record contains multiple x-ray images for which cephalometric data has been digitized, the resulting tracings can be overlaid to indicate changes and/or differences in the anatomy.

Treatment Simulation (VTO) Module provides a tool to simulate orthodontic and surgical treatment results using Visual Treatment Objective (VTO). If a patient's record contains a lateral x-ray head film for which a set of cephalometric landmarks has been defined using the Cephalometric Digitizing Module, this image can be imported into the Treatment Simulation Module to create a simulated post-treatment view for a specific treatment scenario. The Treatment Simulation Module presents the user with a number of operations (orthodontic and surgical) which can be performed on the tracing to bring the patient's anatomy closer to the

established normal values. The result of these operations is a morphed x-ray or photograph of the simulated post-treatment patient. This result is to be viewed as a guideline for the medical professional when making his or her treatment decisions, not as advice or a guaranteed outcome. The resulting image, with its altered cephalometric data, can be stored in the Dolphin Data Storage as a potential treatment scenario. A multiple of these treatment simulation images can be created and stored to serve as a decision-making tool for the medical professional when deciding on a course of treatment.

Arnett/Gunson FAB Analyses performs face, airway, bite analysis, and simulate treatment for orthodontic and surgical cases based on the methodologies of Dr. William Arnett.

The McLaughlin Dental VTO is an interactive treatment-planning and case presentation software program based on the theories of Dr. Richard P. McLaughlin, a renowned clinician, author and lecturer. It analyzes and evaluates tooth positions and dental treatment options, which assists clinicians in planning precise, quantifiable movement of dentition using clinical examination and treatment planning values.

Dolphin Implanner Module is for planning implant procedures. Using this module, simulated dental implants can be placed on a patient's lateral or panoramic x-ray images. Implant data gets written to a section in the image footer for storage.

The Dolphin 3D module contains features for generating a multitude of views of the volumetric data, including simulated x-ray views and 3D-rendered views of the volume. A number of clipping operations can be performed on the volume in order to produce a clear view of the anatomy of interest. Any images generated by the Dolphin 3D module can be stored as snapshots in the Dolphin Data Storage, or sent to the 3D report engine for generated printed output. The Dolphin 3D module contains functions for isolating specific parts of the patient's anatomy for diagnosis, and for placing simulated dental implants. Any view generated in the Dolphin 3D module can be sent to the 3D report engine for formatting and output to printer devices or storage in the Dolphin Data Storage. Reports are designed in a WYSIWYG (What You See Is What You Get) interface and allows free placement of images and text to generate the desired outcome. Images and data items (such as the patient's name, address, and other information) can be automatically imported from the Dolphin Data Storage and included on the report. Reports can be stored in the Dolphin Data Storage using a proprietary XML-based data format and opened from the 2D Image layouts interface at a later date for further manipulation and/or output. Reports can be output

to any installed printer drive device, or as report page snapshots stored as bitmap images on the Windows clipboard or to a hard drive or other storage device.

Dolphin Letter System generates letters that include the images and diagnostic questionnaire data entered by the user. The user can choose a pre-defined letter template or create a custom template.

Dolphin Imaging has similar intended uses as the predicate devices and has very similar technological characteristics. They all allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices. Dolphin Imaging is TWAIN compatible and has the similar 2D functionalities with VistDenat at Complete; DICOM compatible and has the similar 3D functionalities with VitaDent 3D for communication of images with other medical imaging devices.

Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, Dolphin Imaging is substantially equivalent to the predicate devices. Please refer to the Substantial Equivalence Discussion section for detailed comparison.

The software was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating, and maintenance. Dolphin Imaging has successfully completed integration testing/verification testing and Beta validation. In addition, potential hazards have been evaluated and controlled to an acceptable level.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAY 1 1 2011

Ms. Dawn Li, RAC
Regulatory Compliance Specialist
Patterson Dental Supply
1031 Mendota Heights Rd.
SAINT PAUL MN 55120

Re: K110430
Trade/Device Name: Dolphin Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 11, 2011
Received: February 14, 2011

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

3.0 Intended Use Statement

510(k) Number (if known): K110430

Device Name: Dolphin Imaging

Dolphin Imaging software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110430